



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94922d  
Public Health Service

Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

AUG 13 2004

**WARNING LETTER**

**VIA CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

VIRALSOL  
5550 Camino Besar  
Yorba Linda, CA 92887

Dear Sir or Madam:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.viralsol.com> and has determined that the product "VIRALSOL" is promoted for conditions that cause the product to be a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. Although your product is marketed as a dietary supplement, the therapeutic claims on your web site establish that the product is also a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web site include:

- "Extensive in vitro testing has shown that it halts HIV (human immunodeficiency virus) infection in human cells, making it a promising new dietary supplement to help your immune system battle HIV. Viralsol™ has also been shown to exhibit potent antiviral properties against other common viruses, including herpes simplex, influenza, and hemorrhagic fever viruses."
- "Viralsol™'s greatest impact as a dietary supplement will be realized in helping your body fight human viral disease."
- "Herpes Outbreaks: For oral, facial, genital, Epstein-Barr, shingles and other herpes viruses. Recommended Use: Take 2 tablets of dietary-supplement Viralsol™ 3 times daily while outbreak persists. Thereafter, take 1 tablet twice daily to help the body's immune system suppress any recurrence of the infection."
- "Hepatitis-A, B, C: If symptoms occur or diagnosis confirms virus. Recommended Use: Take 2 tablets of dietary-supplement Viralsol™ 4 times daily for 3 – 6 weeks. Thereafter, take 1 tablet twice daily to help the body's immune system suppress any recurrence of the infection."
- "AIDS: Upon detection of the AIDS Virus. Recommended Use: Take 2 tablets of dietary-supplement Viralsol™ 4 times daily until the viral load drops below 5000 (approximately 6 – 18 weeks), decreasing to 2 tablets 3 times daily until viral load is

no longer detectable. Thereafter, take 1 tablet 3 times daily to help your body's immune system maintain that level.

- "Recommended Use: Rhinovirus, Influenza, Herpes, HIV/AIDS."

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

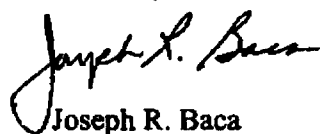
This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

You should take prompt action to correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products.

Please advise this office, in writing and within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to Compliance Officer Kristen L. Moe, 5100 Paint Branch Parkway (HFS-607), College Park, Maryland, 20740-3835.

Sincerely,



Joseph R. Baca  
Director  
Office of Compliance  
Center for Food Safety  
and Applied Nutrition

cc: G & D International Corporation  
2764 Lake Sahara Drive, Suite #111  
Las Vegas, NV 89117